

**NTP Technical Report  
on Toxicity Studies of**

# **Urethane in Drinking Water and Urethane in 5% Ethanol**

**Administered to F344/N Rats  
and B6C3F<sub>1</sub> Mice**

**Po C. Chan, Ph.D., Study Scientist  
National Toxicology Program  
Post Office Box 12233  
Research Triangle Park, NC 27709**

**NIH Publication 96-3937  
March 1996**

**United States Department of Health and Human Services  
Public Health Service  
National Institutes of Health**

## **Note to the Reader**

The National Toxicology Program (NTP) is made up of four charter agencies of the United States Department of Health and Human Services (DHHS):

- the National Cancer Institute (NCI) of the National Institutes of Health;
- the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health;
- the National Center for Toxicological Research (NCTR) of the Food and Drug Administration; and
- the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control.

In July 1981, the Carcinogenesis Bioassay Testing Program was transferred from NCI to NIEHS. NTP coordinates the relevant Public Health Service programs, staff, and resources that are concerned with basic and applied research and with biological assay development and validation.

NTP develops, evaluates, and disseminates scientific information about potentially toxic and hazardous chemicals. This knowledge is used for protecting the health of the American people and for the primary prevention of disease.

NTP designs and conducts studies to characterize and evaluate the toxicologic potential of selected chemicals in laboratory animals (usually two species, rats and mice). Chemicals selected for NTP toxicology studies are chosen primarily on the bases of human exposure, level of production, and chemical structure. The interpretive conclusions presented in this Toxicity Study Report are based only on the results of these NTP studies. Extrapolation of these results to other species and quantitative risk analyses for humans require wider analyses beyond the purview of these studies. Selection *per se* is not an indicator of a chemical's toxic potential.

The studies described in this toxicity study report were performed under the direction of NIEHS and were conducted in compliance with NTP laboratory health and safety requirements. These studies met or exceeded all applicable federal, state, and local health and safety regulations. Animal care and use were in accord and compliance with the Public Health Service Policy on Humane Care and Use of Animals.

Single copies of this report are available without charge, while supplies last, from the NTP Central Data Management (telephone number 919/541-3419).

NTP Central Data Management  
MD E1-02  
NIEHS  
Post Office Box 12233  
Research Triangle Park, NC 27709

**NTP Technical Report  
on Toxicity Studies of**

# **Urethane in Drinking Water and Urethane in 5% Ethanol**

**Administered to F344/N Rats  
and B6C3F<sub>1</sub> Mice**

**Po C. Chan, Ph.D., Study Scientist  
National Toxicology Program  
Post Office Box 12233  
Research Triangle Park, NC 27709**

**NIH Publication 96-3937  
March 1996**

**United States Department of Health and Human Services  
Public Health Service  
National Institutes of Health**

# CONTRIBUTORS

This NTP report on the toxicity studies of urethane in drinking water and urethane in 5% ethanol is based primarily on 13-week studies that took place from December 1990 through April 1991.

## **National Toxicology Program**

*Evaluated experiment, interpreted results, and reported findings*

Po C. Chan, Ph.D., Study Scientist  
John R. Bucher, Ph.D.  
Leo T. Burka, Ph.D.  
June K. Dunnick, Ph.D.  
Michael R. Elwell, D.V.M., Ph.D.  
Joel Mahler, D.V.M.  
Gregory S. Travlos, D.V.M.  
Kristine L. Witt, M.S.  
Oak Ridge Associated Universities

## **TSI Mason Laboratories**

*Principal contributors*

Andrew G. Braun, Sc.D., Principal Investigator  
Christina Gamba-Vitalo, Ph.D.  
Richard Norlin, M.S.  
Frank A. Voelker, D.V.M.

## **Experimental Pathology Laboratories, Inc.**

*Provided pathology quality assessment*

William F. MacKenzie, D.V.M., M.S.

## **Environmental Health Research and Testing, Inc.**

*Provided sperm motility and vaginal cytology evaluation*

Teresa Cocanougher, B.A.  
Dushant K. Gulati, Ph.D.  
Susan Russell, B.A.

## **NTP Pathology Working Group**

*Evaluated slides and prepared pathology report*

Micheal P. Jokinen, D.V.M., Chair  
Pathology Associates, Inc.  
Darlene Dixon, D.V.M., Ph.D.  
National Toxicology Program  
Michael R. Elwell, D.V.M., Ph.D.  
National Toxicology Program  
William F. MacKenzie, D.V.M., M.S.  
Experimental Pathology Laboratories, Inc.  
Joel Mahler, D.V.M.  
National Toxicology Program  
Dave Malarkey, D.V.M. (observer)  
North Carolina State University  
Michael Pino, D.V.M., Ph.D.  
North Carolina State University  
Cynthia C. Shackelford, D.V.M., M.S., Ph.D.  
National Toxicology Program

## **Analytical Sciences, Inc.**

*Provided statistical analyses*

Sarah Rosenblum, M.S.  
Steven Seilkop, M.S.  
Janet L. Teague, M.S.

## **Biotechnical Services, Inc.**

*Provided toxicity report preparation*

Daphne D. Lambright, Ph.D.,  
Principal Investigator  
C. Michael Bailey, B.S. Pharm.  
Waynette D. Sharp, B.A., B.S.

## PEER REVIEW

The draft report on the toxicity studies of urethane in drinking water and urethane in 5% ethanol was evaluated by the reviewers listed below. These reviewers serve as independent scientists, not as representatives of any institution, company, or governmental agency. In this capacity, reviewers determine if the design and conditions of these NTP studies are appropriate and ensure that the toxicity study report presents the experimental results and conclusions fully and clearly.

Robert E. Taylor, M.D., Ph.D.

Department of Pharmacology  
Howard University College of Medicine  
Washington, DC

Lauren Zeise, Ph.D.

Reproductive and Cancer Hazard Assessment Section  
California Environmental Protection Agency  
Berkeley, CA